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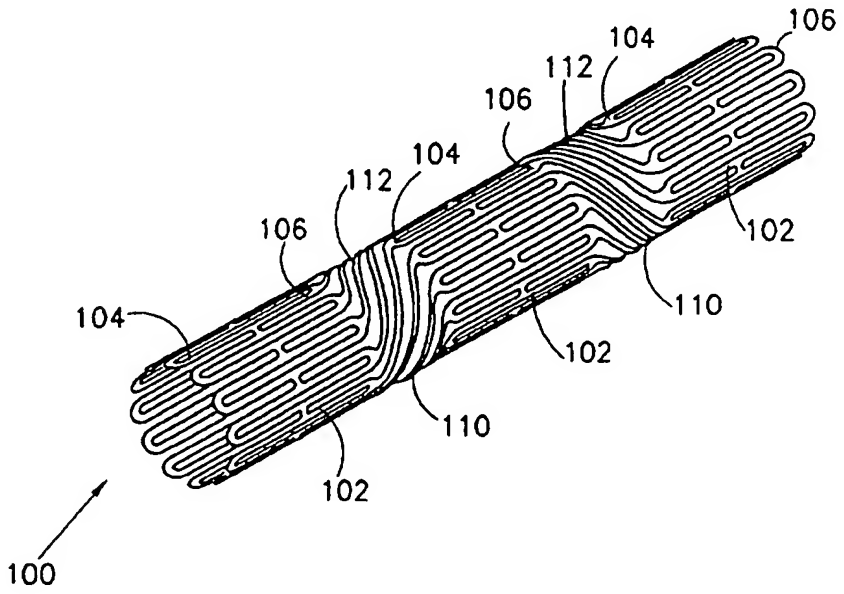
(54) Title: ARTICULATED STENT



(57) Abstract

A connector (110) for connecting adjacent areas of adjacent segments (102) of an articulated stent, the connector includes a plurality of flexible links (112), wherein each of the flexible links includes a plurality of portions with each pair of neighboring portions having an area of inflection therebetween and wherein during expansion of said stent, said area of inflection of each flexible link remains inflected.

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APPLICATION FOR PATENT

Title: ARTICULATED STENT

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to stents which are implanted as part of a balloon angioplasty procedure within a bodily conduit of a living animal or a human to maintain patency. In particular, the present invention relates to articulated intravascular stents for delivery through or implantation in a blood vessel having a curved portion.

Intravascular stents having a constricted diameter for delivery through a blood vessel and an expanded diameter for applying a radially outwardly extending force for supporting the blood vessel are known in the art. Articulated intravascular stents for either delivery through a curved blood vessel or implanted therein are also known in the art.

Self-expandable articulated stents are described, for example, in U.S. Patent No. 5,104,404 entitled "Articulated Stent" to Wolff. Balloon expandable articulated stents are commercially available under the trade name Palmaz-Schatz Balloon-Expandable Stents from Johnson & Johnson Intervention Systems Co.

A prior art self-expandable articulated intravascular stent **10** deployed in a curved blood vessel **16** is now described with reference to Figure 1 which is, in actual fact, Figure 2 of the above referenced U.S. Patent No. 5,104,404. Stent **10** is made up of a number of individual

segments 12 articulated by hinges 14 connected at each end to segments 12. Stent 10 is preferably fabricated from memory shape material, for example, nitinol, and as such is self expandable after delivery from a delivery system described in U.S Patent No. 4,830,003 to Wolff et al. However, these prior art articulated intravascular stents suffer from a number of disadvantages both during delivery through a curved blood vessel and when implanted therein as will now described.

The delivery of stent 10 through curved blood vessel 16 is more complicated than the delivery of a non-articulated stent in that stent 10 has to be angularly oriented such that its hinges 14 are located towards the convex portion of blood vessel 16 so that stent 10 can be flexed inward. In the present example, it will be noted that hinges 14 are located on the same side of segments 12 because blood vessel 16 has only a simple curve in one plane. It can be readily appreciated that delivery of stents through blood vessels which have one or more curved portions which are not in the same plane is even more complicated and generally requires specially constructed stents.

Even when implanted in a curved blood vessel 16, stents 10 are shown to be lacking in that the gaps between segments 12 render the curved portion of blood vessel 16 without support. Furthermore, the gaps at the convex portion of blood vessel 16 are substantially greater than the

gaps at the concave portion thereof, thereby inducing non-uniform and therefore undesirable stresses on blood vessel 16.

Therefore, it would be highly desirable to have an articulated stent which does not require any particular angular orientation when being delivered through a curved bodily conduit and provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted.

It would also be highly desirable the structure of a stent does not depend on the particular orientations of curved portions of a blood vessel.

SUMMARY OF THE INVENTION

The object of the present invention is for an articulated stent which can be delivered through a curved bodily conduit using a routine medical procedure and a conventional stent delivery system. Furthermore, the stent provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted. Still further, the structure of a stent and its support of a bodily conduit do not depend on the orientations of the curved portions of the conduit.

The objective of the present invention is achieved by an articulated stent, comprising: (a) at least two substantially rigid segments; and (b) a flexible connector for connecting adjacent segments, wherein the connector

assumes a substantially cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

After expansion, the rigid segments of the stent preferably present a fine diamond shaped mesh having 1 mm long sides to provide continuous and uniform support for straight portions of a bodily conduit.

The connectors can be implemented as a plurality of substantially helical links connecting adjacent segments. Alternatively, the connectors can be implemented as links each having at least one kink. The connectors typically have between 8-24 links to provide continuous and uniform support for both straight and curved portions of a bodily conduit.

The stents have constricted diameters for intraluminal delivery and are then deformed, by the inflation of a balloon forming part of their catheter delivery system, to expanded diameters for applying radially outwardly extending forces for supporting the lumen of bodily conduits. The constricted and expanded diameters of the stents typically fall in the ranges of 1.0-3.5 mm and 3.5-10.0 mm, respectively.

The stents are preferably fabricated from low memory, more plastic than elastic, bio-compatible materials, for example, stainless steel 316L, gold, tantalum, etc. which enables them to be plastically deformed from their constricted diameters to their expanded diameters.

A typical stent for implantation in a human coronary artery is 9-21 mm long comprising three to seven 2.2 mm long stent segments connected

by two to six 1 mm long connectors such that the ends of the stent subtend between a 45° to 135° angle at a radius of curvature of approximately 9 mm when flexed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 shows a close-up view of a prior art articulated stent of deployed in a curved blood vessel;

FIGS. 2a and 2b show a preferred embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation;

FIG. 2c shows the expanded stent of Figure 2 after plastic deformation;

FIG. 2d shows the stent of Figure 2 mounted on a catheter in its flexed state;

FIGS. 2e and 2f show the stent of Figure 2 before and after expansion by a balloon forming part of its catheter delivery system;

FIGS. 3a and 3b show a second embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation; and

FIG. 3c shows the expanded stent of Figure 3 after plastic deformation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an articulated stent for delivering through a curved bodily conduit, for example, a peripheral or coronary artery of a living animal or a human and implantation therein as part of a balloon angioplasty procedure to maintain patency.

The principles and operation of the articulated stent of the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, Figures 2a-2c show an articulated stent, generally designated **100**, constructed and operative according to the teachings of the present invention, generally comprising a number of substantially rigid segments **102** connected by connectors **110**.

Segments **102** are preferably made up to present a fine diamond mesh of interconnected diamond shaped cells **108** having 1 mm sides on expansion as best seen in Figure 2c. Depending on the intended diameter of stent **100**, segments **102** typically comprise between 8-24 diamond shaped cells **108**.

Connectors **110** comprise links **112** connecting a front end **104** to a tail end **106** of adjacent segments **102**. Links **112** preferably extend in

a substantially helical fashion between apexes of diamond shaped cells **108** at front and rear ends **104** and **106** of adjacent segments **102** such that the number of links **112** equals the number of cells **108**. Links **112** are preferably evenly deployed around perimeters of segments **102** such that connectors **110** can be equally flexed in any direction and to provide continuous and uniform support to both straight and curved portions of a bodily conduit.

Alternate connectors **110** at front and rear ends **104** and **106**, respectively, of a segment **102** preferably have links **112** wound in clockwise and counter clockwise directions. Alternately winding connectors **110** ensures that the rotational displacement of links **112** and adjacent segments **102** relative to the walls of a blood vessel and more importantly the balloon of its delivery system is minimized when stent **100** is expanded.

It is particular feature of the present invention that connectors **110** have a generally cylindrical configuration when stent **100** is relaxed as best seen in Figure 2a and a differentially stretched and compressed curved configuration when stent **100** is flexed as best seen in Figure 2b. The flexed configuration is brought about by two relatively opposing displacements of links **112**. First, the differential stretching of connectors **110** occurs at the convex portion thereof denoted **114** by links **112** being displaced away from one another. Second, the differential compressing of

connectors **110** occurs at the concave portion thereof denoted **116** by links **112** being displaced towards one another.

Stent **100** has a constricted diameter for delivery through a curved bodily conduit as shown in Figures 2a and 2b and an expanded diameter as shown in Figure 2c for supporting a bodily conduit. Stent **100** is preferably fabricated from low memory, more plastic than elastic, bio-compatible material, for example, stainless steel 316L, gold, tantalum, etc. which enables it to be plastically deformed from its constricted diameter to its expanded diameter. The constricted and expanded diameters of stent **100** typically fall in the ranges of 1.0-3.5 mm and 3.5-10.0 mm, respectively.

With reference now to Figures 2d-2f, stent **100** is shown overlying a balloon **118** forming part of its catheter delivery system **120**. Stent **100** is mounted on its catheter delivery system **120** in its constricted diameter state shown in Figure 2e for plastic deformation through inflation of balloon **118** to its expanded diameter shown in Figure 2f for supporting the walls of a bodily conduit. An exemplary stent for implantation in a human coronary artery, is typically 15 mm long made up of five 2.2 mm long segments **102** connected by four 1 mm long connectors **110** and capable of flexion such that its ends subtend a 90° angle at a radius of curvature of approximately 9 mm.

The delivery of articulated stent **100** is considerably simpler than the delivery of prior art articulated stent **10** because stent **100** is equally flexible in all direction and therefore does not require a dedicated angular orientation to pass a particular curved portion. This advantage is particularly important for delivery through blood vessels having multiple curved portions. It is a further advantage of stent **100** over prior art stents **10**, that stent **100** provides continuous and uniform support along the entire length of a blood vessel by means of segments **102** and unflexed connectors **110** supporting straight portions thereof while connector portions **114** and **116** supporting convex and concave curved portions thereof, respectively.

With reference now to Figures 3a and 3b, an articulated stent **122** is shown in which connectors **124** comprise links **126** having one or more kinks **128**. The design of connectors **124** is preferred to that of connector **110** because stent **100** may have a tendency to rupture balloon **118** due to two reasons. First, links **112** overlying the convex portion of balloon **118** have a tendency to be biased inward when stent **100** is flexed. Second, segments **102** display a rotational displacement relative to balloon **118** when stent **100** is expanded.

In this case, the differentially stretched and compressed curved configuration of connector **124** is brought about by two relatively opposing displacements of links **112** as before except that the differential stretching

of connectors **124** at convex portion **114** occurs by kinks **128** being somewhat straightened out while the differential compressing of connectors **124** at concave portion **116** occurs by kinks **128** being more acutely bent.

In a similar fashion to stent **100**, stent **122** has a constricted diameter for delivery through a curved bodily conduit as shown in Figures 3a and 3b and an expanded diameter as shown in Figure 3c for supporting a bodily conduit when implanted therein.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

CLAIMS

1. A connector for connecting adjacent areas of adjacent segments of an articulated stent, the connector comprising:

a plurality of flexible links,

wherein each of said flexible links includes a plurality of portions with each pair of neighboring portions having an area of inflection therebetween.

2. A connector according to claim 1 and wherein, during expansion of said stent, said area of inflection of each flexible link remains inflected.

3. An articulated stent, comprising:

(a) at least two substantially rigid segments having a plurality of connected cells each having apices, wherein, upon expansion, each of said rigid segments presents a substantially cylindrical diamond mesh; and

(b) a flexible connector, comprising a plurality of flexible links

wherein each of said flexible links connects apices of adjacent cells on adjacent rigid segments;

each of said flexible links includes a plurality of portions with each pair of neighboring portions having an area of inflection therebetween, and during expansion of said stent, said area of inflection remains inflected.

4. The stent as in claim 3, wherein said plurality of links includes between 8-24 links.

5. The stent as in claim 3 made from bio-compatible material capable of a more plastic than elastic deformation.

6. The stent as in claim 5, wherein said material is stainless steel.

7. The stent as in claim 5, wherein said material is gold.

8. The stent as in claim 5, wherein said material is tantalum

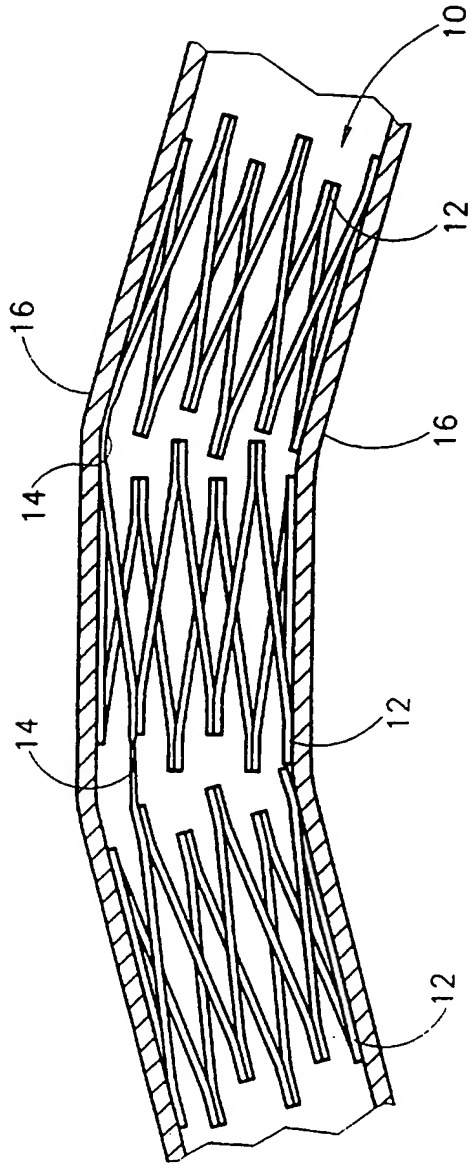


FIG. 1
PRIOR ART

FIG.2A

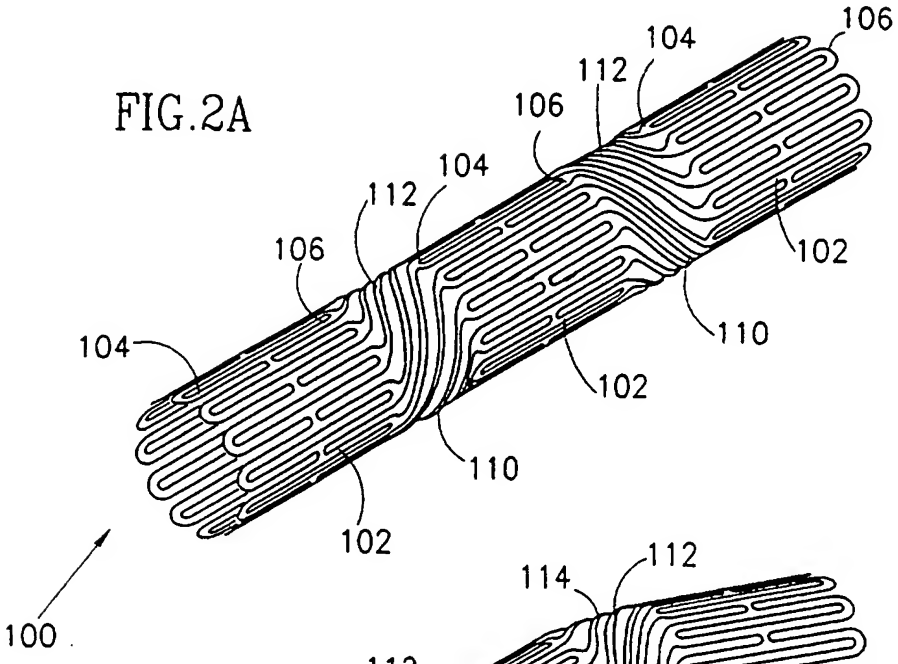


FIG.2B

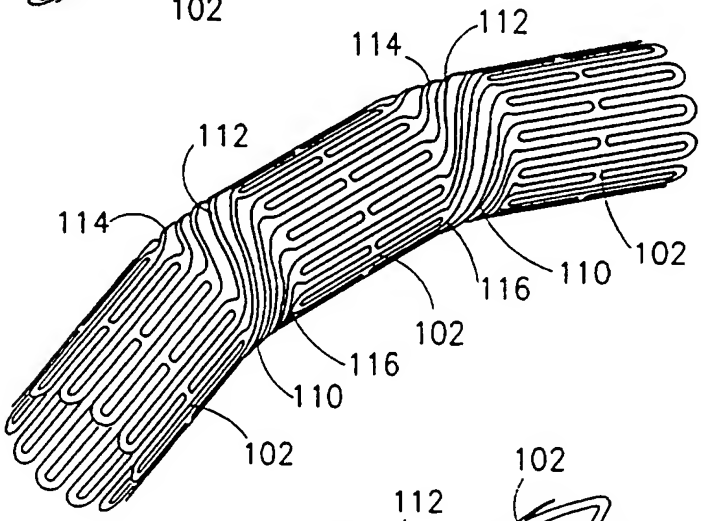
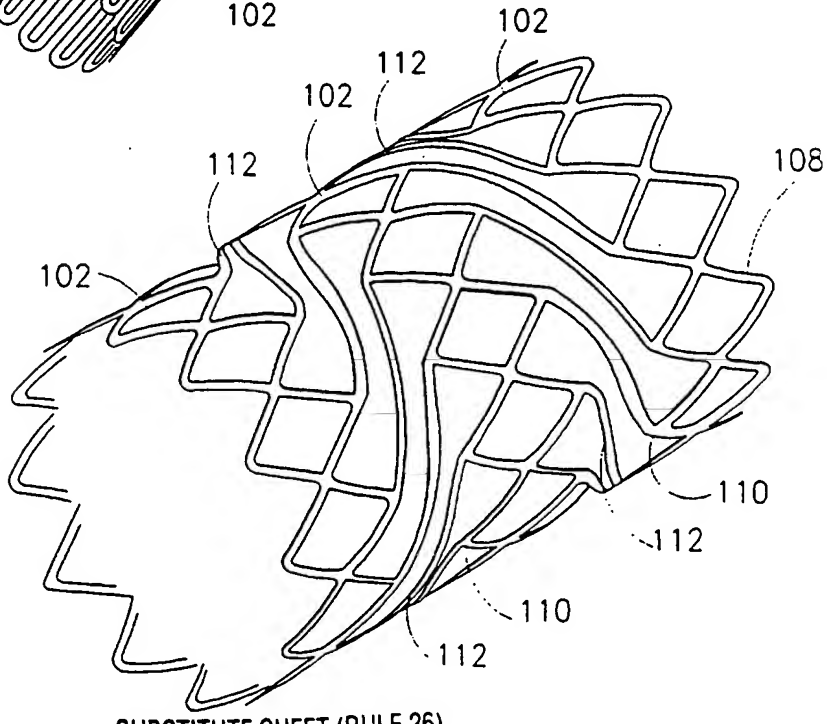


FIG.2C



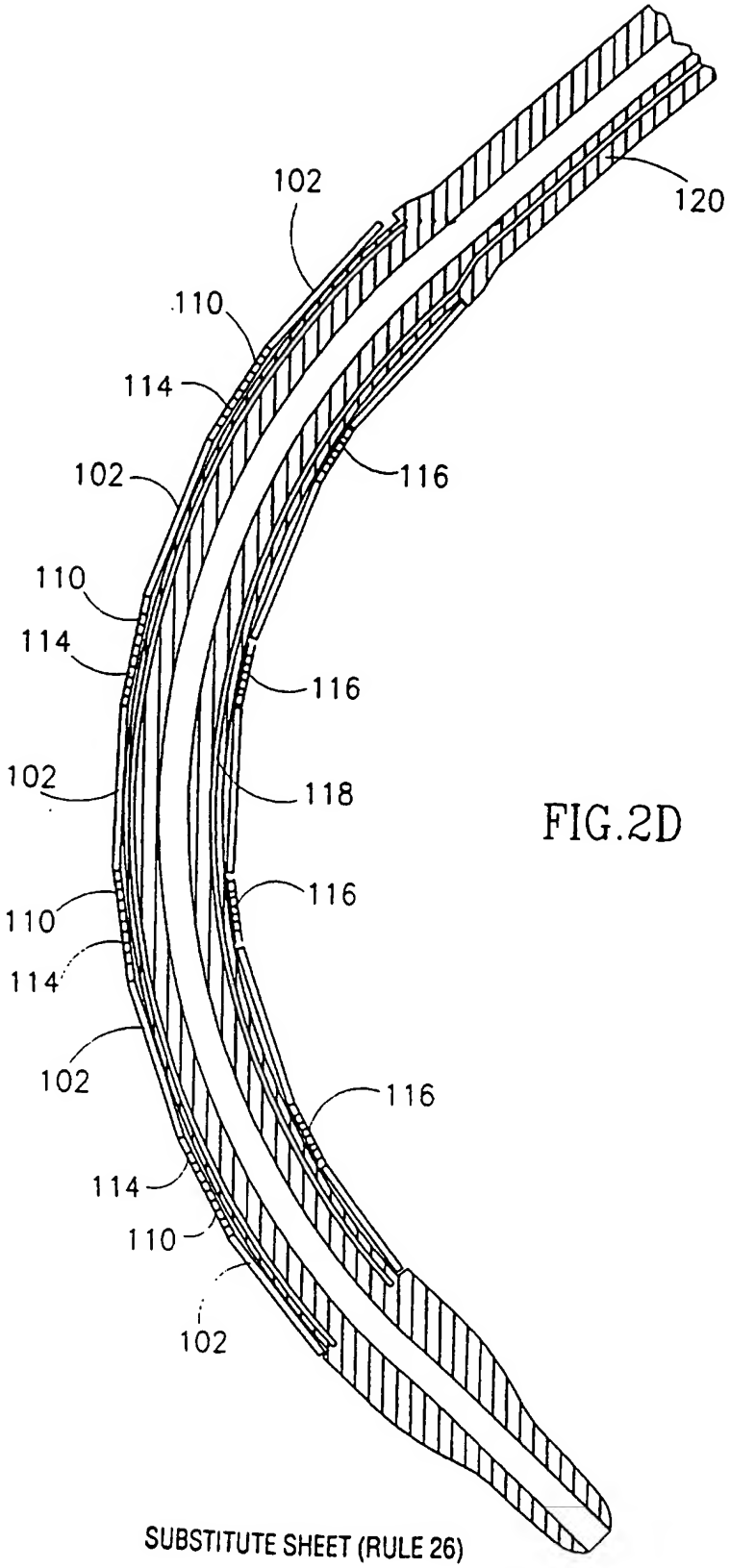

102
120
110
114
102
116
110
114
116
102
118
116
110
114
102
116
114
110
102

FIG.2D

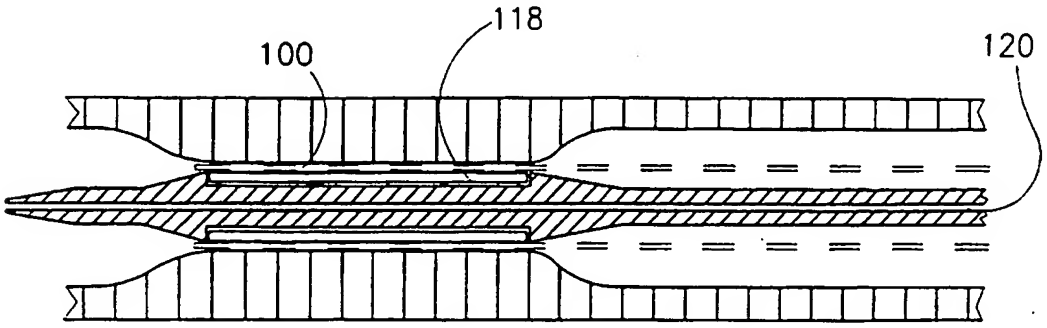


FIG.2E

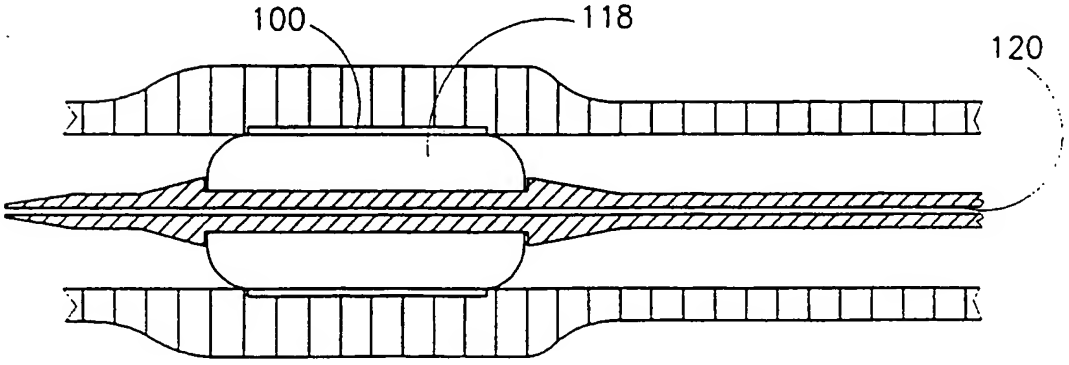


FIG.2F

FIG.3A

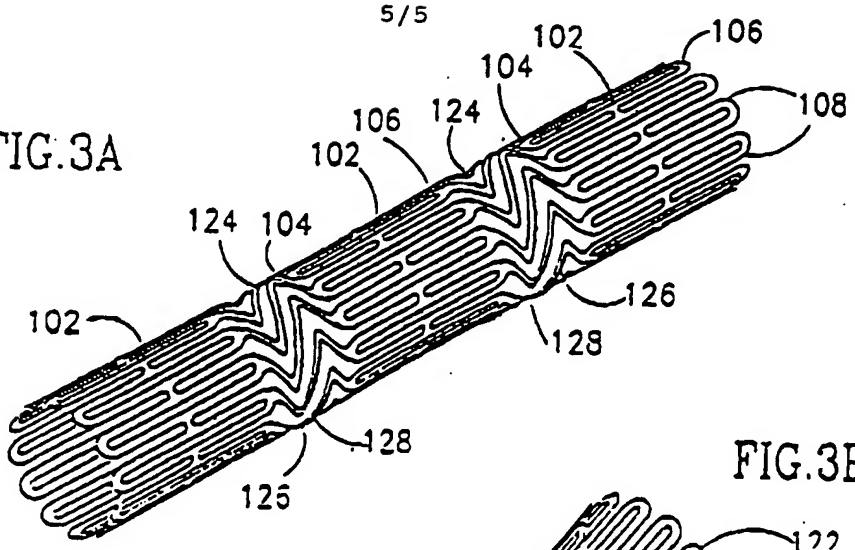


FIG.3B

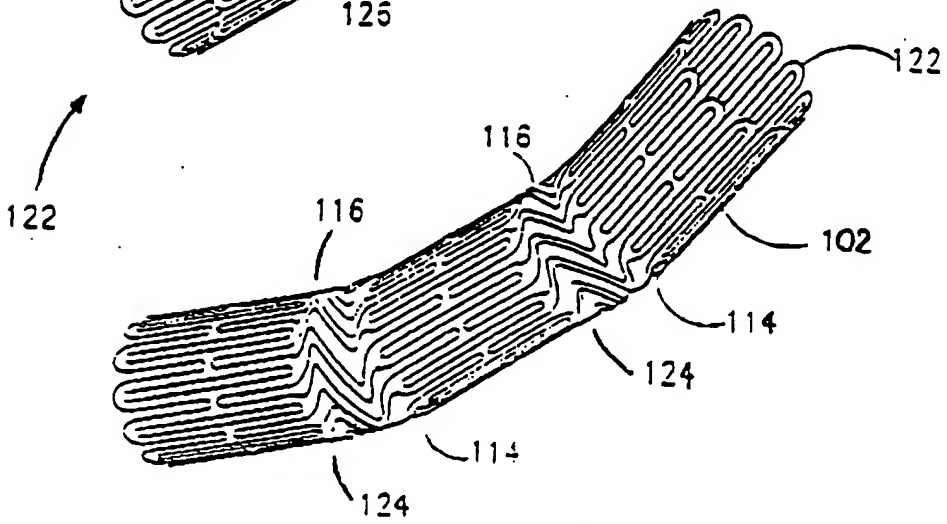
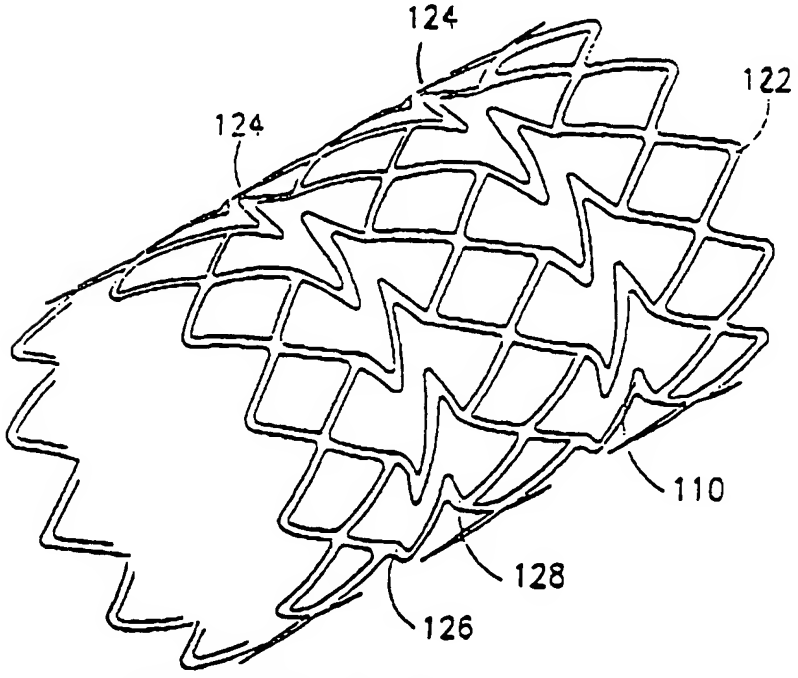


FIG.3C



INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06; A61M 29/02
US CL :606/195

According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/8, 104; 606/195, 194, 198; 623/1, 11, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5,102,417 (PALMAZ) 07 April 1992, see entire document.	1-8

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Date of the actual completion of the international search 10 JUNE 1995	Date of mailing of the international search report 19 JUN 1995
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